ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Various Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	AUTISM MASTER FILE Special Master George Hasting

PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING

The Petitioners' Steering Committee moves the Special Master to issue an order compelling the Respondent to produce documents and make witnesses available for deposition, as described below. This Motion is made on behalf of all petitioners with claims pending in the Omnibus Autism Proceeding, and is made pursuant to Vaccine Rule 7(b), RCFC 26, RCFC 30, RCFC 34, and RCFC 37. This Motion is further supported by the attached Exhibits and Memorandum of Law.

Petitioners seek an Order compelling the production of:

1. Documents requested in Petitioners' Request for the Production of Documents to the CDC, of September 12, 2003, attached as Exhibit A to this Motion.

2. One or more representatives of the National Institutes of Health to appear as an organizational witness for deposition, as requested in Petitioners Notice of Deposition of

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Organization, attached as Exhibit B to this Motion.

3. Documents relating to completed, published studies concerning possible links between thimerosal, the MMR vaccine, or a combination thereof, and the autism disorders at issue in this proceeding. This request is ongoing, and is intended to cover any relevant study that is published during the pendency of this Omnibus Proceeding. Specifically, for any such studies that were initiated, directed, supervised or funded by any federal government entity, or in which an employee of a federal government entity was an investigator or author, petitioners seek production of, or access to:

a.) The datasets or data compilations that the study investigators used or relied on to conduct the study;

b.) The calculations or other interpretive methodologies the study investigators relied on to conduct the study;

c.) Those portions of the files of study investigators, supervisors and sponsors (including the government entity participating in the study) that describe the (i) study's original scope, purposes, and design; (ii) changes to the study's scope, purposes or design that might have occurred during the course of the study; (iii) status reports generated during the course of the study, including reports of progress or problems; and (iv) minutes or any other record of meetings between study investigators or study sponsors during the design of the study, the course of the study and continuing to the present time;

d.) Documents recording any communications between the study's investigators and any other person (whether in or out of the government), concerning the design, progress or status of the study;

e.) All peer-review comments generated in response to the prepublication

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

manuscript;

f.) Documents relating to the government entity's decision to fund, initiate, supervise or otherwise participate in the study, including (but not limited to) requests for bids, requests for grant applications, and all replies or responses thereto, and any received proposed contracts, grant proposals, funding applications, bids, or other requests for funding; and

g.) For any study the government intends to rely on in these proceedings, petitioners seek leave to take the deposition(s) of designated "lead" or "key" study investigator(s), after the relevant background documents regarding the study, as requested herein, have been reviewed by the petitioners.

4. For any studies concerning possible links between thimerosal, the MMR vaccine, or a combination thereof, and the autism disorders at issue in this proceeding *that are in progress or ongoing*, but not yet completed or published, and that were initiated, directed, supervised or funded by any federal government entity, petitioners seek:

a.) Documents describing the scope, purpose, goals, and design of the study, including the data to be relied on and the analytical methodologies and investigative protocols to be employed;

b.) Documents describing the budget and the timeline for the study;

c.) Documents that record any reports of the study's progress, status or problems made by the study investigators to the participating government entity; and

d.) Appearance for deposition of an organizational representative from the participating government entity, with the scope and subject matter for such depositions patterned closely after the CDC and ASTDR depositions already completed by petitioners.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

5. Documents relating to the Thimerosal Screening Analysis (TSA), and access to Vaccine Safety Datalink (VSD) datasets.

a.) To the extent that any study relying on analyses or interpretations of the VSD is published, petitioners seek discovery of documents as described in request No. 3 above, incorporated by reference as if fully set forth here.

b.) To the extent not covered by those requests, petitioners specifically request access to the diagnostic coding of the VSD health maintenance organizations used by the TSA investigators, up to and including the year 2003, and as far into 2004 as the data are available, for the same children already included in the TSA.

c.) Petitioners additionally request that their expert(s) be given access to designated VSD datasets as needed to validate and expand upon the epidemiological VSD analysis conduced by the Drs. Geier, with the data updated to include diagnoses through the present.

6. Those portions of the manufacturers' product license applications (PLAs) that have been withheld or redacted from the PLAs produced by Respondent.

For all of the reasons described in the attached Memorandum of Law, the Special Master should grant each of petitioners' Motions above in their entirety, and enter an Order compelling respondent to produce the requested discovery.

//

//

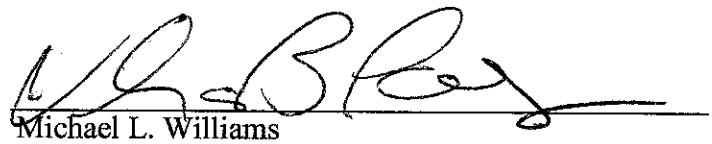
//

//

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

DATED this 8th day of March, 2004.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.

By: 

Michael L. Williams
Thomas B. Powers
Counsel for Petitioners' Steering Committee

Williams Dailey O'Leary Craine & Love, P.C.
1001 SW Fifth Avenue, Suite 1900
Portland, Oregon 97204
(503) 295-2924

CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2004, I served the foregoing **PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING** on the following individuals:

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by United Parcel Service, next morning delivery.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

Brenda D. Steinle , Assistant to Michael L. Williams
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
Washington, D.C. 20045

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Various Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	AUTISM MASTER FILE Special Master George Hasting

MEMORANDUM IN SUPPORT OF PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

TABLE OF CONTENTS

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

TABLE OF AUTHORITIES

Cases

Statutes

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

I. INTRODUCTION

Petitioners submit this Memorandum in support of their Motion to Compel. Petitioners in the Omnibus Autism Proceeding seek the production of documents, access to documents, and depositions relating to the issues of general causation as described in the instant Motion. The Motion and Memorandum are submitted pursuant to the February 9, 2004 Scheduling Order entered by Special Master Hastings.

II. SUMMARY OF THE ARGUMENT

Petitioners' requested discovery should be produced, and petitioners' motion to compel granted, because:

1. The requested discovery is directly relevant to the general causation inquiry at issue in the Omnibus Autism Proceeding, as all of petitioners' requests specifically seek information relating to the possible links between autism injuries and thimerosal, the MMR vaccine, or a combination of both. Contrary to respondent's opposition to the requests, there is nothing overly broad or vague about the requests in petitioners' Motion.

2. Compelling the requested discovery is squarely within the discretion of the Special Master's authority to investigate the facts necessary to reach a decision on general causation, particularly in this Omnibus Proceeding that consolidates thousands of individual claims in one proceeding on general causation. Given the number of claims, the severity of the claimed injuries, and the complexity of the science, it is critical that the petitioners be given access to the discovery sought herein, and that the Special Master have the benefit of the information. Respondent's claims of undue burden and hardship are unavailing in the face of the

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Vaccine Act's explicit interest in providing claimants with a fair process, a process that must include an opportunity to fully develop and put on a case based on the best available information.

3. Petitioners' discovery requests are not barred by the deliberative process privilege as respondent incorrectly attempts to argue. The privilege is not applicable to the requested materials, and respondent has utterly failed to satisfy *any* of the substantive or procedural elements required to properly assert the privilege. Moreover, even if respondent could attempt a showing that the privilege might apply, that privilege is not absolute. Under the relevant law, petitioners can overcome this qualified privilege and the discovery requests should be granted.

4. Petitioners' supplemental discovery requests are reasonable and necessary in light of the developing and expanding scope of scientific inquiry into the questions of general causation at issue in the Omnibus Proceeding. It is critical that the legal inquiry—as reflected in petitioners' supplemental discovery requests—keep pace with the relevant scope of scientific and medical investigation, particularly in instances where the federal government participates in the science, and will rely on the outcome of these studies at the trial on general causation. Respondent cites no legal authority in support of the proposition that the scope of discovery in an Omnibus Proceeding is forever circumscribed by the "state of knowledge" that served as the basis for discovery requests early in the proceeding. There is no merit in respondent's position that petitioners and the Special Master are forever barred from seeking relevant information simply because it was not requested in the original discovery promulgated at the outset of this proceeding.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

III. PROCEDURAL SETTING

The discovery process in this Omnibus Proceeding formally began on August 2, 2002 when petitioners served their initial discovery requests pursuant to Autism General Order #1. In the intervening 18 months respondent has objected to some discovery requests and responded to others. Thousands of pages of documents have been produced (though heavily redacted due to manufacturers' objections to disclosure of "commercially valuable" information to petitioners), primarily consisting of product license applications (PLAs) and vaccine adverse event reports (VAERS). Three depositions of government employees have taken place. The parties have conferred both formally and informally regarding the scope and conduct of discovery in the Omnibus Proceeding. Petitioners will not recount that entire history here, as it is well documented in the record, including the filings of the parties and the Updates and Orders of the Special Master. While the parties have been able to agree on several discovery issues, there are others where the parties are at an impasse. Those contested issues are detailed in the Motion to Compel that this memorandum is appended to, and those issues are the subjects of this memorandum.

Procedurally, the issues are before the Special Master based on "Respondent's Response to Petitioners' Supplemental Discovery Requests and Motion for Enlargement of Time," filed on January 23, 2004 and attached as Exhibit C. This filing was submitted by respondent following an agreement between the parties and approved by the Special Master whereby respondent agreed to 1) summarize the outstanding discovery requests as petitioners' and respondent's counsel had described them in exchanges of emails[1] and telephone conferences, and then 2) respond to those discovery requests. The parties and the Special Master further agreed that

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

respondent's filing would then serve as the basis for petitioners' Motion to Compel, and a briefing schedule was ordered. The instant Motion opens that briefing.

IV. POINTS AND AUTHORITIES

A. The Discovery Sought by Petitioners is Necessary and Relevant to the General Causation Inquiry.

1. The Special Master is Authorized to Conduct the Requested Discovery

Both the Vaccine Act and the Vaccine Court Rules explicitly authorize the Special Masters to conduct discovery in a proceeding on a petition for compensation. 42 U.S.C. §300aa-12(d)(3)(B); Vaccine Rule 7(b) (authorizing the use of the "discovery procedures provided by RCFC 26 – 37" in Vaccine Court proceedings). The Special Master is granted considerable flexibility and discretion to investigate the facts of any claim in the program, including the ability to order discovery. It therefore matters little that discovery is not available "as a matter of right," so long as petitioners can convince the Special Master that the requested discovery—including the taking of deposition testimony and the production of any documents—is "reasonable and necessary" to resolving a material issue in a compensation claim. 42 U.S.C. §300aa-12(d)(3)(B). Respondent's repeated reliance on the lack of discovery as a matter of right is a *non sequiter* that avoids the real question of whether the requested discovery is relevant and necessary to the complex issues of general causation presented in this proceeding.

Petitioners' requests are, on their face, relevant. Petitioners specifically seek only those documents relating to studies or research that involve inquiries into the possible roles of either the MMR vaccine or thimerosal, and the autism injuries at issue. There can be little doubt that both the ongoing and completed studies subject to this discovery request are relevant—

[1] In particular, an email from petitioners' counsel Mike Williams to respondent on January 6, 2004 was intended to summarize the outstanding, contested discovery requests so that respondent could craft a response. That email is attached as Exhibit D.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

respondent itself identified the studies as responsive to petitioners' initial request for production in 2002.[2] Government witnesses have testified at depositions as to ongoing studies. The dispute arises largely because respondent refuses to acknowledge that the *types* of documents requested by petitioners are relevant, and respondent maintains that the only relevant, discoverable documents relating to the studies are the published studies themselves. That position, however, is incorrect.

2. Discovery of the "Background" Documents Relating to Obviously Relevant Studies is Necessary to a Meaningful Consideration of the Scientific Validity and Reliability of these Studies.

The study-related documents requested in petitioners' Motions No. 1, 3, 4 and 5 are relevant to the causation inquiry because the conclusions of a study are inevitably shaped by the manner in which the study was conducted, and petitioners ought to be able to test the validity and limitations of an obviously relevant study by exploring these supporting documents. Contrary to respondent's vague and unsupported claim that all the relevant information "is contained in the published report of the study" (Ex. C, p. 3), answers to critical evaluative questions regarding the methodology and design of a study are ***not*** self-evident.

Moreover, the court needs to make its decision based on a complete analysis of the best available reliable scientific evidence. Unless petitioners are permitted to examine how the conclusions of these studies were shaped by strategic choices of the investigators, there can be severe prejudice to petitioners' ability to challenge the evidence respondent intends to rely on, after respondent created the evidence in secret.

One example of need for access to the requested study documents—particularly documents relating to completed studies as requested in Motions No. 1, 3 and 5—is provided by

[2] See, letters from respondent to petitioners identifying the government studies that respondent averred were responsive to petitioners' First RFP. Exhibit E.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

comparing the "Phase I" and "Phase II" studies conducted by Thomas Verstraeten, et al. Based on analyses of information from selected health maintenance organizations participating in the VSD project, this "Thimerosal Screening Analysis (TSA)" sought to examine the possible link between exposures to thimerosal-containing vaccines and neurological and renal impairment. Without regurgitating the results of the two reports, it is significant that in general the Phase II study reported lower relative risks and less significant statistical associations between thimerosal exposure and neurological injuries than did Phase I. Since epidemiological evidence of the sort generated by the TSA is critically important to the general causation inquiry, it is critically important to develop an explanation of the differences between the two studies.

Some of the differences may be explained by differences in methodology that are self-evident. The second study, for example, included more subjects and a longer observation period than the first—a difference apparent from the published report. Other changes from one study to the next are apparent, but the ***reasons*** for the changes are not self-evident, and need to be explored in order for petitioners' experts and the Special Master to reach meaningful conclusions about the validity of the studies and the weight to give the studies in the general causation inquiry. Specific questions that can only be answered through the requested discovery include:

1. Why did the investigators allow for the disenrollment of children in the second report but not the first?

2. In the second report, the methodology was adjusted to recognize a clinic at one of the HMOs, an adjustment not made in the first report. Since most of the data were obtained from the clinic HMO, this adjustment factor could have a large impact on the study findings and could explain some of the apparent discrepancies between the two reports. It is

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

necessary to know the rationale for the difference in the use of the adjustment factor in the two reports.

3. In the second report, CDC investigators did not analyze combined categories of adverse neurological outcomes as they had done in the first report. Some of the combined findings were statistically significant in the first report. Explaining the different conclusions requires an understanding of the rationale for deciding whether to combine categories of outcomes or not.

4. The second report introduced a requirement that the "control" group of children for the "case" group of children had made at least one visit to a clinic or emergency department at the same month of age as the "case" children, a requirement not included in the methodology of the first report. This change—inexplicable on its face—could have a tremendous bias effect on the results of the study, as the change might over sample sick children, create an unreliable comparison group, and mask any adverse effect of thimerosal exposure on neurological outcomes. Again, this is a change that must be explained if the studies are to be given their appropriate weight.

Similar questions will likely arise whenever petitioners and the Special Master consider the relevant, completed studies as they are published. Questions about the significance of a study's results, the validity of the methodology, whether bias is introduced into a study's methodology, and reconciling the results of various studies all require an inquiry beyond the published results, contrary to respondent's erroneous position. For all of these reasons, petitioners requested discovery in Motions 1, 3 and 4 is reasonable and necessary to resolving the general causation questions at issue, and the Motions should be granted.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

B. Petitioners' Discovery Request is Consistent with Similar Requests for the Discovery of Government Documents that are Made and Granted in Civil Litigation.

While discovery is not a matter of right in the vaccine program, the Special Master is authorized to conduct discovery, as discussed above, pursuant to RCFC 26 – 37. Those rules are in turn modeled on the Federal Rules of Civil Procedure, and in civil litigation conducted under the FRCP the type of discovery of government documents requested by petitioners is permissible.

As an example, U.S. District Court Judge Barbara Rothstein ordered in November 2003 that the FDA produce to the corporate defendant documents relating to the conduct of an epidemiological study involving the relationship between use of the defendant's product (phenylpropanalomine, or PPA) and strokes. While the Opinion and Order (attached as Exhibit F) focuses on whether the deliberative process applied in that case (with the Court rejecting the deliberative process objections raised by the FDA, as will be discussed later in this memorandum), the opinion describes why such documents are important and necessary to a parties ability to put on a case involving complex issues of causation where expert scientific testimony will be critical. Defendant's brief seeking that discovery is also attached (as Exhibit G) because it details the rationale for allowing the requested discovery despite the government's deliberative process objections.

Similar discovery requests were granted over the government's asserted deliberative process objections in multi-district litigation involving diet drugs (*See, e.g., In re: Diet Drugs Product Liability Litigation,* MDL No. 1203, 2000 U.S. Dist., Lexis 15170 (E.D. Pa., October 12, 2000), and similar requests are pending in multi-district litigation involving hormone therapy products. The authors and lead investigators of key studies are regularly deposed in pharmaceutical tort litigation, and litigants have even been given discovery of the medical records of individual subjects involved in key studies. Furthermore, Wyeth recently sought and

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

received permission from the MDL court in Little Rock in the Prempro Drug Products litigation (involving cancers allegedly caused by Hormone Replacement Therapy) to subpoena the background documents and data sources from the NIH of the Women's Health Initiative, the largest single clinical trial study the NIH has ever done.

The procedural and factual contexts of the multi-district product liability litigations where such discovery is held to be relevant and necessary is analogous to the situation faced by the parties and the Special Master in the Omnibus Proceeding. In each case there are hundreds or thousands of individual injury claims related to use of, or exposure to, a particular product. In the MDLs and in the Omnibus Proceeding there are issues of causation common to all claims, or within significant sub-groups of the claims. In each instance the volume of cases would overwhelm the tribunal if adjudicated individually as to every issue of causation, and the claims are thus consolidated for purposes of addressing general causation. Decisions on causation in both the MDLs and in this program will depend heavily on expert testimony, which will in turn rely on analyses of published, relevant studies. Federal judges have been willing to compel the production of "background" material relating to federal scientific research in the MDLs because such information is considered important to one side or the other's ability to develop and present its case.

Those same compelling interests—relevance and necessity—ought to inform these proceedings. Since petitioners have demonstrated that the requested information is of the sort that is relevant and necessary to a thorough inquiry, the Special Master should exercise his discretion to conduct discovery by granting petitioners' Motions and compelling the production of the requested documents and the taking of the requested depositions.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

C. The Deliberative Process Privilege that Respondent Inadequately Raises in Opposition to these Requests does not Bar Production of the Requested Discovery.

Respondent first raised the deliberative process privilege in its September 3, 2002 Response to petitioners' initial requests for production, and respondent continues to claim both formally and in informal communications that it believes the privilege applies so as to bar the requested discovery. As discussed earlier, the parties have since narrowed the contested discovery issues to those outlined in Respondent's Response of January 23, 2004, and the instant Motion. Respondent again asserts the deliberative process objection. The objection should be rejected because respondent utterly fails to satisfy any of the elements necessary to either establish that the privilege applies to the requested documents, or that the privilege, if it applies at all, should bar the requested discovery.

1. Respondent has not Satisfied the Basic Procedural Elements Required to Assert the Privilege.

The deliberative process privilege has its origins in the executive privilege doctrine.[3] *Abramson v. United States,* 39 Fed.Cl. 290, 293, citing *EPA v. Mink*, 410 U.S. 73, 86 (1973), citations omitted. "Within the scope of the executive privilege exists a deliberative process privilege which protects documents 'reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.'" *Id.*

[3] Petitioners do not dispute that the privilege is recognized in the Court of Federal Claims. The deliberative process privilege was first recognized by the United States Court of Claims in 1958 in *Kaiser Aluminum & Chemical Corp. v. United States*, 141 Ct. Cl. 38, 49, 157 F.Supp. 939, 946 (1958). At least one decision since *Kaiser* held that this privilege is not recognized by the Claims Court. *See, State of Alaska v. United States*, 16 Cl.Ct. 5 (1988). However, in *Abramson v. United States*, Judge Miller affirmed that the Court of Federal Claims recognizes the deliberative process privilege. *Abramson*, 39 Fed. Cl. 290, 294 (1997).

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

To properly assert the privilege, courts have held that three procedural requirements must be met: (1) the head of the agency that has control over the requested document(s) or information must assert the privilege after personal consideration; (2) the head of the agency must state with particularity what information is subject to the privilege; and (3) the agency must provide the court with "precise and certain reasons" for maintaining the confidentiality of the requested document(s) or information. *Id.*, . citing *Walsky Constr. Co. v. United States*, 20 Cl.Ct. 317 (1990). Delegation of these procedural requirements to lesser ranking agency officials has been highly debated. The Federal Circuit, however, has held that an official other than the agency head may assert the privilege. *Yankee Atomic Electric Co. v. United States*, 54 Fed. Cl. 306, 310 (2002) ("so high a level of authorization" is not required). "It may be raised by individuals with specific and detailed knowledge of the documents in which the privilege is asserted." *Id.* The U.S. Supreme Court has proposed that this would include permitting the assertion of the privilege by as low a level of official as "any attorney representing the Government." *Id.*, at 310.

While the Department of Justice (DOJ) may therefore have the authority to assert the privilege in this proceeding on behalf of its client agencies, respondent has failed to either state with particularity what information is subject to the privilege, or to provide sufficiently precise and specific reasons for asserting it. Instead, respondent merely repeats the vague and unsupported claim that the requested discovery "may be privileged, or its disclosure otherwise prohibited by law." This bare claim is woefully insufficient under the relevant case law, whether in the Court of Claims or in the federal district courts. *See, e.g., Cobell v. Norton,* 213 F.R.D. 1, 4-5 (D.D.C. 2003) (detailed description of the information subject to the claim is required, as

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

well as detailed explanation for why the privilege applies). Simply claiming that a document was part of a decision-making process and therefore privileged is not enough to meet respondent's burden. *Lurie v. Dept. of the Army,* 970 F.Supp. 19, 33-34 (D.D.C. 1997).

At no point since the privilege was first raised in September 2002 has respondent, or any official of one of its client agencies, offered even a scintilla of evidence identifying any specific document that might be subject to the privilege, nor has there been any explanation whatsoever of why a particular document might be subject to the privilege. There has been no privilege log produced identifying documents for which this privilege is claimed, and there are no affidavits explaining why any document is subject to the privilege. Respondent has the initial burden of proving that the privilege applies. *Cobell,* 213 F.R.D. at 4. Respondent in this case has not begun to meet the basic procedural threshold required to meet their burden, and the objection fails.

2. The Requested Documents are not Covered by the Privilege Because they are Neither "Deliberative" nor "Pre-decisional"

Even if respondent had adequately satisfied the procedural requirements for asserting the privilege, the privilege would not apply here because the requested documents are not "deliberative" in the sense contemplated by the privilege. They are "factual" rather than "deliberative," and thus not privileged.

In order for the deliberative privilege to apply, "a policy-making document must be both pre-decisional and deliberative." *Yankee Atomic Electric*, at 311. "A document is pre-decisional if it precedes, in temporal sequence, the "decision" to which it relates. [Consequently], to approve exemption of a document as pre-decisional, a court must be able to pinpoint an agency decision or policy to which the document contributed." *Abramson*, 39 Fed. Cl. 294. A document

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

is 'deliberative' if it "contains opinions, recommendations, or advice pertaining to agency decisions." Id.

Factual information is not protected by the privilege. *Abramson* at 294; *Yankee Atomic Electric*, at 311. Only information or documents that are "confidential inter-agency memoranda on matters of law or policy" are protected. *National Wildlife Fed'n v. United States Forest Serv.*, 861 F.2d 1114, 1116 (9th Cir. 1988).

Under this standard, none of the requested documents qualify for the privilege. Specifically, Motions No. 1, 3, 4 and 5 request pre-decisional, factual information including datasets, calculations, interpretive methodologies, progress and status reports, information about changes to the study while it was ongoing, design and protocol information, and fact-based explanations for any changes or adjustments made to the studies. None of these requests seek deliberative materials, and none of them seek pre-decisional materials. The only requests for pre-decisional materials are those relating to the government's process for soliciting and awarding bids for potential studies, or otherwise funding such studies. While those documents are pre-decisional, they are not deliberative, as they seek the fact-record supporting decisions to fund or sponsor a given study.

Similarly, the deposition requests regarding the NIH (Motion No. 2), and for depositions of study investigators as the studies are completed (Motion No. 3) do not implicate privileged information. These depositions are *per se* post-decisional, as they could only occur either while a study was under way or after it was completed; that is, the deposition would occur after a decision had been made to conduct the study, and to conduct the study in a particular way.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Finally, it is not clear whether respondent intends to assert the deliberative process as to Motion No. 6, petitioners' request for unredacted product license applications (PLAs). It appears from respondent's Response of January 2004 that other specific objections are raised instead (trade secret, confidential commercial information, personal privacy information) and the deliberative privilege is not mentioned. Petitioners reserve the right to move against the deliberative process objections if specifically asserted by respondent's pending Response to this Motion.

In short, the deliberative process privilege does not apply to any of the requested information in this Motion because petitioners seek fact-based documents and information rather than deliberative information, and because the information sought is not pre-decisional. Respondent fails completely to meet its strict legal burden of showing that the privilege applies at all. Respondent's objection should be rejected, petitioners' Motions should be granted, and the requested discovery should be produced.

3. Even if the Privilege Applied, it is a Qualified Privilege and Petitioners can Overcome the Privilege to Gain Access to the Requested Information.

The privilege is a qualified one; that is, it is not absolute, and may be "overcome upon a showing of evidentiary need weighed against the harm that may result from disclosure." *Abramsom*, 39 Fed.Cl. 290, 295. "Clarifying the nature of 'compelling need', the U.S. Supreme Court in *United States v. Reynolds*, 345 U.S. 1, 11, 73 S. Ct. 528, 533 (1953) explained that "the showing of necessity which is made will determine how far the court should probe in satisfying itself that the occasion for invoking the privilege is appropriate."" *Id.* The court must strike a balance between the Government's interest in frank deliberations and the need for full disclosure in an adversarial process. *Id.*

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Judge Rothstein's Order in the PPA litigation concisely summarizes the "balancing of the interests" analysis in terms applicable to the instant case. Specifically, the Special master here must consider 1) the interest of the petitioners seeking the information, 2) the relevance of the evidence and the availability of other evidence, 3) the role in the litigation of the government entity asserting the privilege, 4) the seriousness of the proceedings, and 5) the public's interest in knowing how effectively the government is operating. Exhibit F, at 5-8.

Here, as detailed above, petitioners have a compelling need for the information and documents requested. All of the information, data and documents sought by petitioners are within the exclusive control of respondents. No same or similar documents, data or information exists, and petitioners cannot obtain it from any other source. Absent the requested data, information and documents, petitioners' experts have no means to verify the data published by various government scientists such as Dr. Verstraeten and Dr. Stehr-Green and relied upon by respondent in claiming that there is no connection between thimerosal and neurological disorders, or between the MMR vaccine and the claimed neurological injuries.

In addition, the government's role in the proceedings is extremely significant, even more so than in the civil cases where the production of government documents has been compelled despite the claim of privilege. Here, of course, the government regulated the products at issue, the government is actively investigating the safety of the products at issue, and the government is a party to the proceedings. Given the pervasive role of the federal government in every aspect of these proceedings, petitioners ought to be able to discovery the requested information.

Further, there is no doubt about the seriousness of these proceedings involving over 3700 children alleging severe and serious neurological and neurodevelopmental injuries.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Finally, the public has an interest in full disclosure of the requested information. First, vaccine-injured children are required by law to seek relief in this forum, and the public has an interest in ensuring that the mandatory administrative program provides claimants with a full and fair opportunity to develop and present their cases. That concern is heightened given the extraordinary caseload represented by the Omnibus Proceeding. The public's faith in the integrity of the program relies on transparency, and the public interest in a perceived fair proceeding is undermined if the government can withhold the requested information. In addition, the public relies on the federal government to appropriately regulate the nation's vaccine program and to provide trustworthy information about vaccines and immunization programs. Again, public trust is undermined when the government pulls a shroud of secrecy over its own scientific proceedings.

By any measure, the balance of the interests weighs overwhelmingly in favor of rejecting the deliberative process privilege objection, granting the petitioners' Motions, and compelling the production of the requested documents.

D. Petitioners Should be Given Access to the VSD Data under a Protocol Developed by Petitioners' Experts, Without the Cost and Delay of the Formal IRB Process.

This issue has been in dispute for 18 months, and at one point was close to resolution by agreement between the parties. At this point, however, respondent clearly objects to petitioners' request that petitioners' experts be allowed access to the VSD data under a protocol designed by petitioners, such access to include data reviewed by a recent research project conducted by Dr. Geier. Respondent maintains that petitioners can access the data only by exhausting the cumbersome and costly procedure pursuant to the "Guidelines for Data Sharing Program for External Researchers: Access to CDC's Vaccine Safety Datalink Data (VSD)."

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

This objection should fail because petitioners are simply not "external researchers" as contemplated by the CDC guidelines. Petitioners and their experts have not received funding to conduct a study, nor are they planning to review the data to publish a peer-reviewed note or report. They are not seeking access to the data in order to satisfy the work product requirements of a university or other research institute. Petitioners are not looking to parlay their access to the data into journal articles, grant proposals, bids for contracts, or any other enterprise. Nothing about petitioners' requested access fits any common-sense definition of what an "external researcher" would do with the data. Instead, petitioners seek access to better determine whether they might have, in fact, been injured by the vaccine products at issue. They seek access to information collected, controlled, stored, managed and studied by the government in order to test the sufficiency of the government's own "causation case" against the petitioners. It is purely a legal fiction to maintain, as respondent insists on doing, that petitioners are merely some disinterested "external researchers" seeking access to the data.

Maintaining this fiction has cost petitioners months of delay in developing their case, and the fiction ought to be discarded and petitioners should be given access to the data. Additional delay imposed by compliance with respondent's objection is not acceptable to petitioners at this stage in the proceedings.[4] To the extent that the government is concerned about the

[4] The CDC process by which "external researchers" can obtain access to CDC datasets is slow and cumbersome, and limits the effectiveness of petitioners' trial preparation. Before access can be granted, an external researcher must (1) submit a proposal to the CDC outlining the proposed project, the researchers/investigators, a summary of the project purpose and public health benefits, and methods of proposed analytic study; (2) (a) must submit an application for review and approval to the Institutional Review Boards of the participating health maintenance organizations for use of the VSD datasets identifying the proposed project and the manner in which the external researcher plans to maintain the confidentiality of all data, and (b) provide a copy of the IRB approval to the CDC before the CDC will "begin the process of creating and/or formatting the approved datasets; and (3) pre-pay the CDC for a minimum of two consecutive days of use of "work stations with computers" at the CDC. The cost for a two-day minimum use is $3,208.85. Each additional day of use is charged at $779.58 per day, also to be paid in advance.

Once permitted access to the CDC's RDC, external researchers my only work under the supervision of approved CDC staff, may only use the computers pre-loaded with approved datasets by the CDC technicians, may not bring into the RDC any personal equipment such as cell phones, pagers, computers, etc that would allow them to

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

confidentiality of identifying information contained in the data, petitioners will agree to permit a "third-party audit" of the data to remove potentially identifying personal information, and petitioners will agree to any other confidentially provisions designed to protect the integrity of patient privacy. Other than that, petitioners should be given access to the data under a protocol of petitioners' design.

E. The High Level of Scientific Activity Relating to the Issues in this General Causation Inquiry Support the Production of the Requested Discovery.

Respondent repeatedly insists that no further discovery should be conduced in this proceeding because the requested discovery was not requested during the original discovery planed over one year ago. That position is not supported by any legal authority, and it defies reality. This is not a single claim involving a discrete injury to a single child arising from one shot, where the injury is generally similar to other reported injuries associated with the same product. While the vaccine compensation program's traditionally limited, brief and narrow discovery makes sense for such a claim, it makes no sense in this proceeding involving over 3700 claims of severe injuries, presenting complex and novel issues of science and medicine. There has been a veritable explosion of scientific research into many of the issues relating to this general causation inquiry—justice, fairness, thoroughness and procedural rigor require that these legal proceedings keep pace with the relevant science.

Cutting off discovery before the science is complete, or limiting discovery so as to preclude inquires into the reliability, validity and weight of the science that is complete, cannot be justified merely because the current scope of discovery was not contemplated at the outset of the proceeding. Such an outcome would represent the triumph of form over substance.

---

communicate with anyone outside of the CDC RDC. Only two external researchers may be permitted access at a time. See Guidelines for Data Sharing Program for External Researchers: Access to CDC's Vaccine Safety Datalink Data, www.cdc.gov/nip/vacsafe/vsd/VSDGuidelines.txt.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Petitioners current requests are specific, relevant and necessary. Respondent's objections are vague, unsupported by legal authority, and not supported by any showing whatsoever of hardship or burden. As such, the objections are insupportable, and they should be rejected.

V. CONCLUSION

For all of the above reasons, each of petitioners Motions to Compel should be granted in their entirety, and the Special Master should order the production of the requested discovery.

DATED this 8th day of March, 2004.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.

By: 

Michael L. Williams
Thomas B. Powers
Counsel for Petitioners' Steering Committee

Williams Dailey O'Leary Craine & Love, P.C.
1001 SW Fifth Avenue, Suite 1900
Portland, Oregon 97204
(503) 295-2924

CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2004, I served the foregoing **MEMORANDUM IN SUPPORT OF PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING** on the following individuals:

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by United Parcel Service, next morning delivery

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

Brenda D. Steinle , Assistant to Michael L. Williams
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
Washington, D.C. 20045

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)